In re Application of: Bobrowski, Paul
Serial No.: 10/674,587
Atty. Docket No.: PHMC0745-021

Art Group: 1655
Examiner: Susan B. McCormick-Ewoldt

Amendment dated 2/13/2006
Reply to the Final Office Action of Dec. 12 2005

REMARKS/ARGUMENTS

Claim Status

1. Claims 1-2, 4-10 and 20-29 are pending.

Claim Rejections - 35 USC § 103

Tempesta and Nikiliza obviousness rejection

2. The Examiner maintained the rejection of claims 1-2, 4-10, and 20-29 under 35 USC §103(a) as being "unpatentable over Tempesta (US 5,494,661) and Nkiliza (US 5,928,646)."

3. The Examiner writes at page 2 of the office action:

> Tempesta (US 5,494,661) discloses extracting proanthocyanidins from *Croton* species (column 8, lines 25-27). The Croton latex was subjected to partitioning by ethyl acetate and water (column 10, lines 38-39). It was also extracted with isopropanol and evaporated to dryness by in vacuo (column 13, lines 45-56). Tempesta also disclose the wavelength range between from 202 nm to 600 nm (column 1-3). Tempesta does not disclose using a drying agent such as magnesium sulfate or sodium sulfate.
>
> Nkiliza (US 5,928,646) disclose extracting proanthocyanidins using ethyl acetate and drying agents such sodium sulphate and magnesium sulphate and the evaporation step is carried by lyophilization (column 1, lines 12-14; column 3, lines 4-10, 17-18).

4. The Examiner then argued that "even if the method [claimed by the applicant] was not the particular one carried out [by the cited reference], *it shows that the method was being done* ***and*** one skilled in the art would be motivated to attempt separate the lipophilic components from the hydrophilic components and retain the lipophilic components because of the beneficial properties of the lipophilic components such as being able to be absorbed more readily." (Office action, pg. 3.)

In re Application of: Bobrowski, Paul
Serial No.: 10/674,587
Atty. Docket No.: PHMC0745-021

Art Group: 1655
Examiner: Susan B. McCormick-Ewoldt

Amendment dated 2/13/2006
Reply to the Final Office Action of Dec. 12 2005

Tempesta and Nikiliza obviousness rejection

5. The Examiner also rejected claims 1-2, 4-10, 20-29 under 35 USC §103(a) as being unpatentable over "Tempesta (US 5,494,661), Nkiliza (US 5,928,646) and WO 00/47062." (Id., pg. 3)

6. Relying on the Examiner's earlier opinion(s) and/or argument(s) regarding Tempesta and Nkiliza, the Examiner further writes:

> WO 00/47062 discloses obtaining latex from croton species by separating the liquid phase and solid phase with a solvent. WO 00/47062 discloses the use of several different methods of evaporation such as evaporated drying and spray drying. WO 00/47062 also discloses the additional UV absorption between 400 nm to about 500 nm. (see sections 4.1, 4.1.7, 4.1.8.1).
>
> Therefore, a person of ordinary skill in the art would reasonably expect that the solvents and drying agents used in the proanthocyanidin extraction of Nkiliza could be used in the proanthocyanidin extraction of Tempesta as well as the sue of several different method of evaporation. Based on this reasonable expectation of success, a person or ordinary skill in the art would be motivated to make these modifications to Tempesta.

(Id.)

Applicant's Rebuttal

7. The following citation of legal precedent is exemplary of legal authority supporting the Applicant's arguments.

8. The Applicant respectfully alleges that the Examiner has not established a prima facie case under 35 USC 103. To establish a *prima facie* case of obviousness; there must be: 1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art reference (or references when combined) must teach or suggest all

the claim limitations. MPEP 2143. Further, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added). Moreover, if the proposed modification to the prior art would change the principle of operation of the prior art invention being modified, then the teachings are insufficient to render the claimed combination obvious. MPEP 2143 VI, *citing In re Ratti*, 270 F.2d 810 (CCPA 1959). Finally, simply because prior art references can be combined or modified does not render the combination obvious unless the prior art also suggestions the desirability of the combination. MPEP 2143 III, *citing In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. See MPEP 2142.

Lack of Prima Facie basis for rejection

9. The Examiner has failed to establish a proper prima facie case for the rejections under 35 USC §103 referenced in this response at paragraphs 2 - 6 above.

10. The Examiner's argument relies on an improper suggestion or motivation to combine the references. The Examiner's suggestion or motivation to combine the references comes either from hindsight, the applicant's disclosure, and/or from the alleged level of skill in the art. The Examiner at page 3 of the office action reasons that the prior art shows the level of skill in the art (i.e. "that the method was being done in the prior art") and that "one skilled in the art would be motivated to attempt separate the lipophilic components from the hydrophilic components and retain the lipophilic

components because of the beneficial properties of the lipophilic components such as being able to be absorbed more readily." (Office action, pg. 3.)

11. However, because the cited prior art references fail to mention the "beneficial properties of the lipophilic components" or provide a reasonable expectation of successfully obtaining an extract with beneficial properties, the rejection is improper. *See In re Vaeck*, at 493-94 (Fed. Cir. 1991). The only suggestion of beneficial properties or of an expectation of successfully obtaining an extract with "beneficial properties" comes directly from the applicant's disclosure - and improper hindsight. Likewise, the level of skill in the art cannot serve as a motivation to combine the references. See MPEP 2143.01 I. and IV. *citing, Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). In other words, simply because something can be done does not also provide the basis for why one should do it.

12. Moreover, each of the prior art references, including WO 00/47062, cited by the Examiner teaches toward the concentration of the aqueous proanthocyanidin components (and not the lipophilic fraction of an organic extraction of Croton plant material or latex) and thus away from the concentration of the lipophilic fraction as claimed by the applicant. See MPEP 2143.01 V. and VI. It also follows that the modification of any of the references as suggested by the Examiner would improperly and substantially (if not completely) change and contradict the principle of operation or teachings of the reference(s). Id.

13. The applicant respectfully requests a withdrawal of the rejection. Alternately, in preparation for drafting an appeal brief, the applicant requests a clarification of the Examiner's reasoning supporting the alleged "motivation to combine" including a specific indication of where in the prior art do the reference(s) mention the "beneficial properties of the lipophilic components"

or provide a reasonable expectation of successfully obtaining an extract with beneficial properties. Finally, if the Examiner's argument relies entirely or in part on the argument that lipophilic components are more readily absorbed, the Applicant requests an affidavit under 37 CFR 1.104(d)(2).

14. Finally, the combination of prior art references also fails to disclose all the elements as claimed by the applicant. The applicant has claimed a method of making an extract of croton species with concentrated lipophilic components. In contrast, each of the Examiner's cited references discloses an extract of croton species with concentrated proanthocyanidin components. Thus, *even if* modified as suggested by the Examiner, the teachings of the references would fail to disclose all the claimed elements of the applicant's invention (i.e. an extract of croton species with concentrated lipophilic components).

15. More so, the applicant in claims 8, 9, 25, 28, and 29 require a specific reduced relative level of proanthocyanidin content. As basis for a rejection, the Examiner alleges, "WO 00/47062 also discloses the additional UV absorption between 400nm to about 500nm. (see sections 4.1, 4.1.7, 4.1.8.1)." (Office action, pg. 3). However, the full context of the disclosure cited by the Examiner's reveals the characteristics of a Croton species extract with concentrated proanthocyanidin content and certainly not the reduced relative level of proanthocyanidin content claimed by the applicant.

16. Thus, the applicant respectfully requests a withdrawal of the rejection; or alternatively, in preparation for appeal, a clarification of the Examiner's argument regarding how and where the cited references disclose either: i.) a Croton species extract with a non-specific reduction of proanthocyanidin content; or ii) a Croton species extract with the specific relative reduction of proanthocyanidin content claimed by the applicant in claims 8, 9, 25, 28, and 29.

In re Application of: Bobrowski, Paul
Serial No.: 10/674,587
Atty. Docket No.: PHMC0745-021

Art Group: 1655
Examiner: Susan B. McCormick-Ewoldt

Amendment dated 2/13/2006
Reply to the Final Office Action of Dec. 12 2005

Conclusion

The applicant has responded to each issue raised by the Examiner's office action and requests either clarification or withdrawal of the 35 USC §103 rejections.

Respectfully submitted,

Ellis & Venable

Date: 2/13/2006

By: Michael F. Campillo
Michael F. Campillo, Reg. No. 44583

Attorneys for Applicant
101 North First Avenue, Suite 1875
Phoenix, Arizona 85003-1910
(602) 631-9100

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. (571) 273 - 8300 on 2/13/2006.

Signature: Michael F. Campillo

Typed or printed name of person signing this certificate: Michael F. Campillo